REMARKS

Favorable reconsideration is respectfully requested in view of the foregoing amendments and the following remarks. A 132 Declaration is attached to this response.

I. CLAIM STATUS AND AMENDMENTS

Claims 1-20 were pending in this application when last examined. Applicants note that the Office had previously indicated that claims 1-18 were pending. Applicants respectfully request the Office to indicate the pending claims in the next Office Action.

Claims 1-20 were examined on the merits and stand rejected.

Claims 1-9 and 14-20 are cancelled without prejudice or disclaimer thereto. Applicants reserve the right to file a continuation or divisional application on any cancelled subject matter.

Claim 10 is amended to correct a typographical error.

Claims 21-27 are newly added. Support for these claims can be found in claims 3-8, 15 and 17 of the specification as filed.

No new matter has been added.

II. FOREIGN PRIORITY

In item 12 on page 1 of the Office Action, the Examiner acknowledged the claim for foreign priority, but did not indicate whether the priority documents have been received. Applicants respectfully request the Examiner to acknowledge such by checking the appropriate boxes in item 12 (a-c) and (1-3).

III. 112/101 REJECTIONS

In item 3 on page 2 and in item 4 also on page 2, claims 18-20 were rejected under 35 U.S.C. 112 and 35 U.S.C. 101. These claims have been cancelled and therefore these rejections are moot.

IV. ENABLEMENT AND WRITTEN DESCRIPTION REJECTIONS

In item 5 on pages 2-5, claims 15-17 were rejected under 35 U.S.C. § 112, first paragraph, on the basis that the specification lacks enablement for a method of treating the wide

variety of sleep disorders with the broad number of compounds claimed.

Applicants note that claims 15-17 have been cancelled and therefore this rejection is moot. Applicants further note new claims 21-27 are methods of preventing and/or treating sleep disorders with the compound of claim 10. Applicants submit that these new claims are fully enabled by the specification.

Further, in item 6 on pages 5-9, claims 1-9 were rejected under 35 U.S.C. § 112, first paragraph, on the basis that the specification lacks written description support for the genus of agonist claimed.

Applicants note that claims 1-9 have been cancelled and therefore this rejection is moot.

V. OBVIOUSNESS REJECTION

On pages 9-17, claims 10-14 were rejected under 35 U.S.C. § 103(a) as obvious over Jenck et al. (Proceedings of the National Academy of Sciences, Vol. 97, No. 9, pp. 4938-4943, 2000), Ito et al. (US 6,423,725), and Tulshian et al. (WO 2000006545).

Applicants respectfully traverse this rejection.

Compound (I) of the claims has strong affinity for an ORL-1 receptor and weak affinity for a μ receptor. Due to this feature, the claimed compound is useful for treatment of sleep disorders and the like. Such is not expected from the cited references.

The problem of existing benzodiazepine sleeping drugs is their dependency properties. For example, since drugs such as Triazolam and the like cause dependency at usual doses, the use thereof is strictly limited (long-term prescription exceeding 2 weeks is prohibited). Hence, sleeping drugs should not have any dependency properties. It is known that μ receptor agonists represented by morphine cause strong dependency. There are two types of dependency, i.e., mental dependency and physical dependency. Since μ receptor agonists cause strong physical dependency, discontinuation thereof results in withdrawal symptoms. It is therefore certain that a compound having a μ receptor agonistic activity cannot be a long term sleeping drug.

From the foregoing, a selective ORL-1 receptor agonist showing strong affinity for an ORL-1 receptor and weak affinity for a μ receptor should be a safe sleeping drug free of dependency problems.

To establish the selective and strong affinity of compound (I) of the present invention for an ORL-1 receptor, we herein submit a Declaration reporting on the comparative experiments

between compound (I) and the compounds of the cited references (compound on page 4940, Fig. 1 of Jenck et al; compound of Example 17 of Ito et al.; 1st compound in Table 5 on page 38 and compound at the lowermost line of page 60 of Tulshian et al.). As is clear from the results, the compound of the present invention shows strong affinity for an ORL-1 receptor and weak affinity for μ receptor, as compared to the compounds of the cited references (see the Table in the Declaration).

As described above, compound (I) of the present invention has a superior effect that is unexpected from the cited references because it shows a selective and strong affinity for an ORL-1 receptor.

Therefore, Applicants respectfully submit that the cited references fail to teach or suggest the claimed invention because they fail to teach or suggest the surprising and unexpected high affinity for ORL-1 receptor and weak affinity for μ receptor of the claimed compound. Therefore, Applicants respectfully suggest this rejection is untenable and should be withdrawn.

VI. ANTICIPATION REJECTION

On page 17, claims 1-9 were rejected under 35 U.S.C. § 102(b) as being anticipated by compound A of Biorganic and Medicinal Chemistry Letters, Vol. 9, pp. 2343, 1999.

Claims 1-9 are cancelled and therefore this rejection is moot. Further, the new claims are limited to compounds of formula (I) which do not encompass compound A of the cited reference. Moreover, the cited reference discloses compounds having anxiolytic properties but not compounds effective for the treatment of sleep disorders, like the claimed compounds.

VII. CONCLUSION

In view of the foregoing amendments and remarks, it is respectfully submitted that the present application is in condition for allowance and early notice to that effect is hereby requested. If the Examiner has any comments or proposals for expediting prosecution, please contact the undersigned attorney at the telephone number below.

Respectfully submitted,

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